

**IN THE SPECIFICATION:**

Please replace the paragraph beginning at page 2, line 3, with the following:

*B1* In drug delivery applications, it is typically desirable to provide an aerosol having average mass median particles diameter of less than 2 microns to facilitate deep lung penetration. Additionally, it is desirable, in certain drug applications, to deliver medicaments at high flow rates (i.e., above 1 milligram per second). Devices for controlling the flow rate of an aerosol are known. For example, U.S. Patent No. 4,790,305 concerns controlling the particle size of a metered dose of aerosol for delivery to the walls of bronchi and bronchioles by filling a first chamber with medication and a second chamber with air such that all of the air is inhaled prior to the inhaling of medication, and using flow control orifices to control the flow rate. U.S. Patent No. 4,926,852 relates to metering a dose of medication into a flow-through chamber that has orifices to limit the flow rate to control particle size. U.S. Patent No. 3,658,059 discloses a baffle that changes the size of an aperture in the passage of the suspension being inhaled to select the quantity and size of particles delivered. A problem associated with these devices is that they process the aerosol after it is generated and are inefficient and wasteful.

Please replace the paragraph beginning at page 4, line 23 with the following:

*B2* FIG. 5 shows details of a first heater element pattern, which can be used for a resistance heating layer in the heater shown in FIG. 4;

Please replace the paragraph beginning at page 4, line 25 with the following:

B<sup>3</sup> FIG. 6 shows details of a second heater element pattern, which can be used for a resistance heating layer in the heater shown in FIG. 4;

Please replace the paragraph beginning at page 6, line 1 with the following:

B<sup>4</sup> In accordance with a preferred embodiment of the invention, chamber 10 is constructed from a material (e.g., polymeric, aluminum foil) resistant to heating. For example, in the embodiment shown in FIGS. 1 and 2, the chamber 10 is formed as a recess 12 in an injection molded body 14 of polymer material and a flow passage 30 comprises a channel 16 in the body 14, the channel 16 extending from the recess 12. The chamber 10 is sealed by a layer 18 ~~such as aluminum foil heat sealed to the~~ plastic body 14.

Please replace the paragraph beginning at page 6, line 8 with the following:

B<sup>5</sup> In order to provide multiple doses of medicated fluid in a disposable part of an inhaler, the plastic body 14 can include a plurality of recesses 12. The laminate thus described is capable of withstanding the pressure applied to the interior of the chamber through the application of heat necessary to vaporize the fluid contained therein. Outlet 20 is preferably a small aperture at the end of the flow passage 30, the outlet being initially closed to the atmosphere. The flow passage 30 can have any suitable size which is effective to expel the vaporized fluid into the atmosphere and form the aerosol of desired droplet size. For instance, flow passage 30 can have an inside diameter of about 0.05 to about 0.60 millimeter, preferably about 0.2 mm and a length of about 50 to 200 times the

B5 inside diameter. The chamber 10 can have any desired size such as a size suitable to deliver a single dose of medicated fluid, e.g., 5 $\mu$ l.

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Please replace the paragraph beginning at page 7, line 7 with the following:

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B6 The flow passage 30 can have any desired configuration. For instance, the flow passage can have a uniform cross-sectional area along the length thereof between the chamber 10 and the outlet 20. However, the flow passage can vary in size along the length thereof, e.g., tapered so as to become more narrow in a direction towards the outlet 20. Further, the chamber 10 need not comprise a concave circular recess, but rather, can comprise any desired configuration sized to accommodate a single dose of the medicated fluid.

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Please replace the paragraph beginning at page 9, line 9 with the following:

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B7 With reference to FIGS. 3-6, a fluid delivery system is depicted, wherein individual disposable aerosol generators are transported to a fluid release position as required by the user. Inhaler device System 100 includes a cartridge 110 loaded with disposable aerosol generators 120. In a preferred embodiment, the aerosol generators 120 are provided in the form of packets, preferably constructed as described above in connection with FIGS. 1 and 2. A heating device 130 provides sufficient energy to each generator 120 to vaporize the fluid and expel the vaporized fluid through a passage in a dispenser 140. An opening device 150 can comprise a puncture element 152 ~~150~~ activated by a solenoid 145, the

67 puncture element 152 being operable by a suitable controller and circuitry to penetrate the layer 18 in the vicinity of outlet 20.

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Please replace the paragraph beginning at page 10, line 3 with the following:

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69 FIGS. 5 and 6 show embodiments of different heater patterns for the heater 130. The heater 130a shown in FIG. 5 includes a heating element 132a configured to completely cover the chamber 10 and flow passage 30. With the heater element pattern shown in FIG. 5, greater heating can be achieved in the flow passage 30 due to the smaller cross sectional area of the heating element along the flow passage. The heater 130b ~~132b~~ shown in FIG. 6 includes a heating element 132b configured as a sinusoidally shaped strip which overlies chamber 10 and a rectilinear strip which overlies the flow passage 20.

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Please replace the paragraph beginning at page 10, line 11 with the following:

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69 In operation, the disposable cartridge 110 can be loaded into the inhaler device 100, and a transport mechanism (not shown) can be operated to successively transport the aerosol generators to the release position at which the heater volatilizes the fluid contained in the respective chamber. Driving power for the transport mechanism, the solenoid and the heating element can be provided by a power source such as a 9-volt battery. The dispenser 140 can be arranged to supply the vaporized fluid to a mouthpiece (not shown) of the inhaler device 100.

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Please replace the paragraph beginning at page 10, line 18 with the following:

B<sup>10</sup> FIG. 7 shows an embodiment of an inhaler device 200 having a disposable cartridge and modified piercing mechanism and FIGS. 8 and 9 show details of the disposable cartridge usable therein.

Please replace the paragraph beginning on page 10, line 26 and ending on page 11, line 13 with the following:

B<sup>11</sup> The cartridge 300 rotates on a spindle 216. The spindle 216 is biased in contact with spindle cam 218 by spring 220 and the spindle cam 218 is driven in rotation by shaft 226. A piston 222 located below a reservoir discharging position is movable vertically by a cam 224 driven in rotation by shaft 226. A motor 228 drives a first gear 230 which in turn drives a second gear 232. The second gear 232 is connected to shaft 226 thereby causing rotation of shaft 226. As a result of rotation of shaft 226, spindle cam 218 lifts spindle 216 ~~218~~ such that flange 219 on spindle 218 raises the cartridge 300. When the cartridge 300 is raised, puncture element 234 pierces an outlet in a flow passage 312 and piston 222 is pressed against a reservoir 310 in fluid communication with the flow passage 312 at a rate effective to cause liquid to flow into the flow passage 312 at a desired flow rate, e.g., a constant flow rate. The flow passage 312 is preferably of capillary size, e.g., a maximum width of 0.01 to 10 mm, preferably 0.05 to 1 mm, more preferably 0.1 to 0.5 mm. Alternatively, the capillary passage can be defined by transverse cross sectional area of the passage which can be  $8 \times 10^{-5}$  to  $80 \text{ mm}^2$ , preferably  $2 \times 10^{-3}$  to  $8 \times 10^{-1} \text{ mm}^2$  and more preferably  $8 \times 10^{-3}$  to  $2 \times 10^{-1} \text{ mm}^2$ .

Please replace the paragraph beginning at page 11, line 14 with the following:

B12 During operation of the inhaler device 200, liquid in the flow passage 312 is vaporized and the vaporized liquid passes out of the pierced outlet so as to form an aerosol in the mouthpiece 210. To maximize heating of the flow passage, the flow passage 312 is held against heater 236 by the raised spindle 216. The heater can be activated prior to when the fluid is forced into the flow passage 312 by the piston 222.

Please replace the paragraph beginning at page 12, line 1 with the following:

B13 Operation of the inhaler device 200 can be controlled by a programmable controller 244. The controller 244 is preferably programmed to control operation of motor 228 and heater 236 as described above. The controller can be programmed to keep track of how many reservoirs have been dispensed and provide such information to a display (not shown). A switch and/or sensor such as a puff actuated sensor (not shown) can be used to detect a delivery condition indicating a user is ready to inhale the vaporized liquid. In response to the sensed condition, the controller 244 actuates the motor 228 and heating element 236. A battery 246, or other power source, can be used to provide power to the controller 244, motor 228 and heater 236.

Please replace the paragraph beginning at page 13, line 6 with the following:

B14 To maintain the fluid in the reservoirs, the cartridge can include layers of material covering upper and lower surfaces thereof. For example, a film 318 can be used to cover the lower ~~bottom~~ surface of the cartridge, e.g., the film 318 can cover a single reservoir or

64 all of the reservoirs by covering the entire lower surface of disposable cartridge 300. The film 318 is preferably made from polymer material and has a thickness of less than 0.007 inches. Another layer such as a foil 322 can be used to cover the flow passages 312 of the disposable cartridge 300. The foil 322 can cover an individual flow passage or the entire upper surface of disposable cartridge 300. The foil 322 is preferably aluminum foil having a thickness of less than 0.003 inches. An aluminum foil can be easily punctured piercing by the puncture element 234 and is heat resistant so as to withstand the heat emanating from heater heating element 236.

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